PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

PRIVETT, Kathryn, Louise
SmithKline Beecham
Corporate Intellectual Property
(CN9.25.1)
980 Great West Road
Brentford, Middlesex TW8 9GS
ROYAUME-UNI

Date of mailing (day/month/year)
21 February 2002 (21.02.02)

Applicant's or agent's file reference
FB/BM45398

IMPORTANT NOTIFICATION

International application No.
PCT/EP00/07281

International filing date (day/month/year)
27 July 2000 (27.07.00)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address

PRIVETT, Kathryn, Louise
Corporate Intellectual Property
SmithKline Beecham
Two New Horizons Court
Brentford
Middlesex TW8 9EP
United Kingdom

State of Nationality:

State of Residence:

Telephone No.
+44 208 975 6294

Facsimile No.
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Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address

PRIVETT, Kathryn, Louise
SmithKline Beecham
Corporate Intellectual Property
(CN9.25.1)
980 Great West Road
Brentford, Middlesex TW8 9GS
United Kingdom

State of Nationality:

State of Residence:

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Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Dominique DELMAS

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:
PRIVETT, Kathryn, Louise
Corporate Intellectual Property
SmithKline Beecham
Two New Horizons Court
Brentford
Middlesex TW8 9EP
ROYAUME-UNI

Date of mailing (day/month/year)	
08 February 2001 (08.02.01)	
Applicant's or agent's file reference FB/BM45398	**IMPORTANT NOTICE**

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/EP00/07281	27 July 2000 (27.07.00)	30 July 1999 (30.07.99)

Applicant
SMITHKLINE BEECHAM BIOLOGICALS S.A. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AU,KP,KR,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AG,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EA,EE,EP,ES,
   FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,
   MN,MW,MX,MZ,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,
   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   08 February 2001 (08.02.01) under No. WO 01/09330

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 23 March 2001 (23.03.01)	
International application No. PCT/EP00/07281	**Applicant's or agent's file reference** FB/BM45398
International filing date (day/month/year) 27 July 2000 (27.07.00)	**Priority date** (day/month/year) 30 July 1999 (30.07.99)
Applicant THONNARD, Joelle	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

03 February 2001 (03.02.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

CLAIMS:

1. An isolated polypeptide comprising an amino acid sequence which has at least 85% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4, over the entire length of SEQ ID NO:2 or SEQ ID NO:4 respectively.

2. An isolated polypeptide as claimed in claim 1 in which the amino acid sequence has at least 95% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4, over the entire length of SEQ ID NO:2 or SEQ ID NO:4 respectively.

3. The polypeptide as claimed in claim 1 comprising the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4.

4. An isolated polypeptide of SEQ ID NO:2 or SEQ ID NO:4.

5. An immunogenic fragment of the polypeptide as claimed in any one of claims 1 to 4 in which the immunogenic activity of said immunogenic fragment is substantially the same as the polypeptide of SEQ ID NO:2 or SEQ ID NO:4.

6. A polypeptide as claimed in any of claims 1 to 5 wherein said polypeptide is part of a larger fusion protein.

7. An isolated polynucleotide encoding a polypeptide as claimed in any of claims 1 to 6.

8. An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide that has at least 85% identity to the amino acid sequence of SEQ ID NO:2 or 4 over the entire length of SEQ ID NO:2 or 4 respectively; or a nucleotide sequence complementary to said isolated polynucleotide.

9. An isolated polynucleotide comprising a nucleotide sequence that has at least 85% identity to a nucleotide sequence encoding a polypeptide of SEQ ID NO:2 or 4 over the entire coding region; or a nucleotide sequence complementary to said isolated polynucleotide.

10. An isolated polynucleotide which comprises a nucleotide sequence which has at least 85% identity to that of SEQ ID NO:1 or 3 over the entire length of SEQ ID NO:1 or 3 respectively; or a nucleotide sequence complementary to said isolated polynucleotide.

11. The isolated polynucleotide as claimed in any one of claims 7 to 10 in which the identity is at least 95% to SEQ ID NO:1 or 3.

12. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2 or SEQ ID NO:4.

13. An isolated polynucleotide comprising the polynucleotide of SEQ ID NO:1 or SEQ ID NO:3.

14. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2, SEQ ID NO:4 obtainable by screening an appropriate library under stringent hybridization conditions with a labeled probe having the sequence of SEQ ID NO:1 or SEQ ID NO:3 or a fragment thereof.

15. An expression vector or a recombinant live microorganism comprising an isolated polynucleotide according to any one of claims 7 - 14.

16. A host cell comprising the expression vector of claim 15 or a subcellular fraction or a membrane of said host cell expressing an isolated polypeptide comprising an amino acid

sequence that has at least 85% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4.

17. A process for producing a polypeptide of claims 1 to 6 comprising culturing a host cell of claim 16 under conditions sufficient for the production of said polypeptide and recovering the polypeptide from the culture medium.

18. A process for expressing a polynucleotide of any one of claims 7 – 14 comprising transforming a host cell with the expression vector comprising at least one of said polynucleotides and culturing said host cell under conditions sufficient for expression of any one of said polynucleotides.

19. A vaccine composition comprising an effective amount of the polypeptide of any one of claims 1 to 6 and a pharmaceutically acceptable carrier.

20. A vaccine composition comprising an effective amount of the polynucleotide of any one of claims 7 to 14 and a pharmaceutically effective carrier.

21. The vaccine composition according to either one of claims 19 or 20 wherein said composition comprises at least one other *Moraxella catarrhalis* antigen.

22. An antibody immunospecific for the polypeptide or immunological fragment as claimed in any one of claims 1 to 6.

23. A method of diagnosing a *Moraxella catarrhalis* infection, comprising identifying a polypeptide as claimed in any one of claims 1 - 6, or an antibody that is immunospecific for said polypeptide, present within a biological sample from an animal suspected of having such an infection.

24. Use of a composition comprising an immunologically effective amount of a polypeptide as claimed in any one of claims 1 – 6 in the preparation of a medicament for use in generating an immune response in an animal.

25. Use of a composition comprising an immunologically effective amount of a polynucleotide as claimed in any one of claims 7 - 14 in the preparation of a medicament for use in generating an immune response in an animal.

26. A therapeutic composition useful in treating humans with *Moraxella catarrhalis* disease comprising at least one antibody directed against the polypeptide of claims 1 – 6 and a suitable pharmaceutical carrier.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organizati n
International Bureau

(43) International Publication Date
8 February 2001 (08.02.2001)

PCT

(10) International Publication Number
WO 01/09330 A3

(51) International Patent Classification[7]: C12N 15/31, C07K 14/21, A61K 39/02, C07K 16/12, G01N 33/53, A61K 31/70, 39/40

(21) International Application Number: PCT/EP00/07281

(22) International Filing Date: 27 July 2000 (27.07.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9918040.8 30 July 1999 (30.07.1999) GB

(71) Applicant *(for all designated States except US)*: SMITHKLINE BEECHAM BIOLOGICALS S.A. [BE/BE]; Rue de l'Institut 89, B-1330 Rixensart (BE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: THONNARD, Joelle [BE/BE]; SmithKline Beecham Biologicals s.a., Rue de l'Institut 89, B-1330 Rixensart (BE).

(74) Agent: PRIVETT, Kathryn, Louise; Corporate Intellectual Property, SmithKline Beecham, Two New Horizons Court, Brentford, Middlesex TW8 9EP (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

(88) Date of publication of the international search report:
5 July 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/09330 A3

(54) Titl : MORAXELLA CATARRHALIS ANTIGEN BASB121

(57) Abstract: The invention provides BASB121 polypeptides and polynucleotides encoding BASB121 polypeptides and methods for producing such polypeptides by recombinant techniques. Also provided are diagnostic, prophylactic and therapeutic uses.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
FB/BM45398		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 00/ 07281	27/07/2000	30/07/1999
Applicant		
SMITHKLINE BEECHAM BIOLOGICALS S.A.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [X] contained in the international application in written form.

   [X] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   MORAXELLA CATARRHALIS ANTIGEN BASB121

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [X] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/[redacted]00/07281

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/31 C07K14/21 A61K39/02 C07K16/12 G01N33/53
A61K31/70 A61K39/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C07K A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE EMBL 'Online! Entry/Acc.no. AE001406, 9 November 1998 (1998-11-09) GARDNER M.J. ET AL: "Plasmodium falciparum chromosome 2, section 43 of 73 of the complete sequence." XP002157305 the whole document	8-10,14, 15
A	WO 97 32980 A (LOOSMORE SHEENA M ;SCHRYVERS ANTHONY B (CA); CONNAUGHT LAB (CA); Y) 12 September 1997 (1997-09-12)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 January 2001	26/01/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Smalt, R

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/[redacted]00/07281

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9732980 A	12-09-1997	US 6090576 A	18-07-2000
		AU 722681 B	10-08-2000
		AU 1865397 A	22-09-1997
		BR 9710435 A	17-08-1999
		CA 2248095 A	12-09-1997
		CN 1217748 A	26-05-1999
		EP 0885300 A	23-12-1998
		JP 2000503855 T	04-04-2000
		NZ 331777 A	29-09-1999

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SH/FB/BM45398		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/07281	27/07/2000	30/07/1999
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03/02/2001	23.10.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Stegen, C Telephone No. +49 89 2399 7804

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/07281

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-67 as originally filed

Claims, No.:

1-26 as received on 06/08/2001 with letter of 03/08/2001

Drawings, sheets:

1/6-6/6 as originally filed

Sequence listing part of the description, pages:

66-67, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-26
	No:	Claims	none
Inventive step (IS)	Yes:	Claims	1-4, 6-18, 23
	No:	Claims	5, 19-22, 24-26
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	none

2. Citations and explanations
   see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

R It m I

Basis

The Applicant filed amendments with the letter dated 03.08.2001. These amendments meet the requirements of Article 34(2)(b) PCT and form the basis of the present international preliminary examination report.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Documents

Reference is made to the following documents:

D1: DATABASE EMBL [Online] Entry/Acc.no. AE001406, 9 November 1998 GARDNER M.J. ET AL: 'Plasmodium falciparum chromosome 2, section 43 of 73 of the complete sequence.'

D2: WO 97 32980 A (LOOSMORE SHEENA M ;SCHRYVERS ANTHONY B (CA); CONNAUGHT LAB (CA); Y) 12 September 1997

1. Novelty

The invention is based on the cloning of the BASB121 coding sequence of *Moraxella catarrhalis*. The amino acid and nucleotide sequences SEQ ID NO: 1 to 4 as such are considered novel, as is the subject-matter of the claims directed to it.

The clarifying amendments of claims 8-10 and 14 establish novelty claims 8 to 10, 14 and 15. Thus, the subject-matter of claims 1 to 26 is considered novel over the prior art.

2. Inventive step

Among the cloned genes of M. catarrhalis several have been identified as coding for "surface antigens", such as UspA1 and UspA2 (see present application p.5, l.4-17), and the transferrin receptor (D2).

2.1 The basis of the present invention seems to be the "surface antigen" BASB121-polypeptide, the polynucleotide encoding it and an antibody raised against it (see claims 1-18, 22). The applicant claims that these products are useful for diagnosis, vaccination and therapy (see claims 19-21, 23-26).

2.2 Document D2, which is considered to represent the most relevant state of the art, discloses the sequence of transferrin receptor gene of *M. catarrhalis*, which can be used e.g. to derive hybridization probes for diagnostic purposes.

2.3 In the light of the prior art the technical problem to be solved can be seen as the provision of a further surface antigen suitable for diagnostic purposes, vaccination and therapy.

2.4 The Applicant provides the amino acid sequences of the surface antigen BSAB121- and the DNA sequence encoding it. However, the discovery of an antigenic protein may be useful for diagnostics (e.g. by detecting antibodies against this protein in blood samples), but it does not necessarily mean that the antigen gives rise to a protective immune response. Therefore, its suitability for vaccination and therapy is not per se obligatory. As the examples given in the description do not sufficiently support this suitability for vaccination and therapy the technical problem is considered to be only partially, i.e. in respect to diagnostic use, solved. In the present application no convincing solution to the technical problem of therapy and vaccination has been found (see also Item VIII(a)). No inventive step can be acknowledged for claims for which no solution to a technical problem, which makes a contribution over the prior art, can be recognized.

2.5 Thus, the Applicant provides a solution only for the problem of the provision of further diagnostic means, which is represented by claims 1-4, 7-18 and 23. These are based on the DNA and amino acid sequence of BSAB121 which are novel and which had neither been anticipated nor rendered obvious by the prior art. Therefore, the said solution is considered novel and inventive, meeting the requirements of Article 33(3) PCT. However, the subject-matter of claims 5 19 to 22 and 24 to 26 is objected for lack of inventive step.

Re Item VIII

Certain observations on the international application

(a) Article 5 PCT

Apart from above mentioned BASB121-related products (claims 1-18, 22) the applicant claims a vaccine, a pharmaceutical composition and the use of the polypeptide and the polynucleotide for the preparation of a medicament (claims 19-21, 23-26). However, the present application does not provide sufficient disclosure of the latter subject-matter (claims 19-21, 23-26). In the description there are several experimental procedures described which can be used to evaluate the immunological characterization of BASB121-polypeptide and its potential use as a vaccine (p.60-63, Examples 5-11). However, no immunogenic fragment or epitope is identified. In addition, there is no experimental proof provided, that there is a protective immune response induced by a vaccine comprising the polypeptide or the polynucleotide.

(b) Articl 6 PCT

Claim 5 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem: "An immunogenic fragment....in which the immunogenic activity of said immunogenic fragment is substantially the same as the polypeptides of SEQ.....". The technical features necessary for achieving this result, i.e. the sequence of such a fragment, should be added. Arbitrary expressions such as "substantially the same" should be avoided.